Remarks

Claims 1-10, 14, 16-20, 24 and 35-37 are pending and under examination. Applicant has herein cancelled claims 2-9 without prejudice or disclaimer to applicant's right to pursue the subject matter of these claims in the future. In addition, applicant has amended claims 35-37. Support for the amendments to claim 35 can be found in the specification as originally filed at, inter alia, page 25, line 28 to page 26, line 4. Claim 36 has been amended merely to correct its dependency from claim 35. Support for the amendments to claim 37 can be found in the specification as originally filed at, inter alia, page 26, lines 8-11. Applicant has also added new claims 43-50 directed to Examiner's claim group V. Support for new claim 43 can be found in the specification as originally filed at, inter alia, page 14, lines 14-22; page 16, lines 10; page 26, lines 8-9. Support for new claim 44 can be found in the specification as originally filed at, inter alia, page 26, lines 13-14. Support for new claim 45 can be found in the specification as originally filed at, inter alia, page 51, line 11; page 30, line 3; page 22, lines 26 to 29; page 24, lines 23-26; page 3, lines 7-10; and at page 29, lines 13-14. Support for new claims 46-48 can be found in the specification as originally filed at, inter alia, page 30, line 3; page 24, lines 23-26; and page 33, lines 5-10. Support for new claim 49 can be found in the specification as originally filed at, inter alia, page 22, line 31 to page 23, line 4; page 11, line 2; and page 11, lines 3 and 4. Support for new claim 50 can be found in the specification as originally filed at, inter alia, page 22, line 31 to page 23, line 4. Applicant maintains that that the amendments to the claims raise no issue of new matter.

Restriction Requirement Under 35 U.S.C. §121

The October 18, 2006 Office Action imposes a restriction requirement under 35 U.S.C. §121 of the claims among the following five (5) allegedly independent and distinct inventions:

I. Claims 1-9, drawn to a method of treating a disorder of a subject's heart comprising administering a composition an amount of a human stromal-derived factor and human granulocyte-colony stimulating factor. The Examiner stated that the election of this group requires the further election of a single human stromal-derived factor-1 selected from the group consisting of 1α, 1β, and 1γ; AND a single molecule selected from the group consisting of a human granulocyte macrophage-colony stimulating factor, a human interleukin-8, a human vascular endothelial growth factor, a human fibroblast growth factor, a human Gro family chemokine, human endothelial progenitor cells, or a pro-angiogenic agent. The Examiner also stated that election of this group also requires the further species election of a disorder from the group consisting of myocardial infarction, congestive heart failure, chronic ischemia or ischemic factor, AND the further species election of a single mode of administration selected from the group consisting of intramyocardially, via a stent, via a scaffold of via slow release formula;

II. Claims 10, 14, 16-19, drawn to a method of treating a disorder of a tissue involving loss and/or apotosis of cells of the tissue comprising administering a composition comprising an amount of an agent which induces phosphorylation and/or activation of protein kinase B. The Examiner also stated that election of this group requires the further election of a single agent selected from the group consisting of insulin, endothelin-1, urocrotin, cardiotropin-1, erythropoietin, leukemia inhibitory factor-1, and tumor necrosis factor-alpha, AND the further election of a single a human granulocyte macrophage-colony stimulating factor, a human stromal-derived factor-1, a human granulocyte macrophage-colony stimulating factor, a human interleukin-8, a human vascular endothelial growth factor, a human fibroblast growth factor, a human Gro

family chemokine, human endothelial progenitor cells, or a pro-angiogenic agent, for reasons provided below. The Examiner stated that election of this group also requires the further species election of a single tissue from the group consisting of heart muscle, striated muscle, liver, kidney, neuronal or gastrointestinal tissue;

III. Claim 20, drawn to a composition comprising a human stromal-derived factor-1 and a human granulocyte-colony stimulating factor;

IV. Claim 24, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss and/or apoptosis of cells of the tissue which comprises administering to the subject a composition comprising an amount of an agent which induces phosphorylation and/or activation of an extracellular signal-regulated protein kinase, the composition being administered in an amount effective to inhibit apoptosis and/or cause proliferation of the cells of the tissue within the subject so as to thereby treat the disorder; and

V. Claims 35-37, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss and/or apoptosis of cells of the tissue which comprises administering to the subject a composition comprising an amount of an agent which induces activation of CXCR4, the composition being administered in an amount effective to cause proliferation of the cells and/or inhibition of apoptosis of the cells of the tissue within the subject so as to thereby treat the disorder. The Examiner stated that election of this group requires the further species election of a single route of administration selected from the group consisting of intramyocardially, intracoronarily, via a stent, a scaffold.

The Examiner asserted that, inter alia, claim groups III and I are related as a product and process of use. The Examiner also asserted that claim groups I, II, IV and V are directed to related processes. The Examiner further stated that the alleged inventions are distinct if (1) the inventions as claimed are not capable of

use together or can have a materially different design, mode of operation, function or effect; (2) the inventions do not overlap in scope, i.e. are mutually exclusive, and (3) the inventions as claimed are not obvious variants, and that in the instant case the inventions as claimed each have different designs and effects.

In response to this restriction requirement, applicant hereby elects, with traverse, to prosecute the invention of Examiner's claim group V, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss and/or apoptosis of cells of the tissue which comprises administering to the subject a composition comprising an amount of an agent which induces activation of CXCR4. In addition, in response to the Examiner's species requirement, applicant hereby elects, with traverse, the species intramyocardially for prosecution on the merits.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction requirement be withdrawn in view of the fact that the claims of Groups I-V are not independent.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect...". The claims of Group I-V are related in that they are drawn to similar compounds, compositions, and methods of use. All of the methods relate to treating or preventing a disorder of a tissue involving loss of cells.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to any of Groups I-V would identify art for the other Groups. Since there is no serious burden on the Examiner to examine Groups I-V in the subject application, the Examiner must examine the entire application on the merits.

Applicant maintains that the pending claims define a single inventive concept. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine the pending claims on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number

provided below.

No fee, apart from the enclosed total fee of $425.00, including a $225.00 fee for a two-month extension of time and $200.00 claim fees, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents
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Alexandria, VA 22313-1450

John P. White 1/5/07

John P. White Date
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